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TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number	10/828,827
Filing Date	4/21/2004
First Named Inventor	Max R. Motyka
Art Unit	1616
Examiner Name	Ernst V. Arnold
Attorney Docket Number	00015-22306

ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
  - [x] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please Identify below):
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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Thorpe North & Western, LLP		
Signature			
Printed name	Gary P. Oakeson		
Date	12/04/2007	Reg. No.	44266

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2008

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($)	255.00

Complete if Known	
Application Number	10/828,827
Filing Date	4/21/2004
First Named Inventor	Max R. Motyka
Examiner Name	Ernst V. Arnold
Art Unit	1616
Attorney Docket No.	00015-22306

METHOD OF PAYMENT (check all that apply)

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	310	155	510	255	210	105	
Design	210	105	100	50	130	65	
Plant	210	105	310	155	160	80	
Reissue	310	155	510	251	620	310	
Provisional	210	105	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	210	105
Multiple dependent claims	370	185

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 20 or HP =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 3 or HP =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $260 ($130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____	/ 50 = _____ (round up to a whole number)	x _____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Appeal Brief	255.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 44266	Telephone (801) 566-6633
Name (Print/Type)	Gary P. Oakeson		Date 12/04/2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANT:	Motyka et al.
SERIAL NO.:	10/828,827
FILING DATE:	04/21/2004
CONF. NO.:	5229
FOR:	HYPOALLERGENIC METAL AMINO ACID CHELATES AND METAL AMINO ACID CHELATE-CONTAINING COMPOSITIONS
ART UNIT:	1616
EXAMINER:	Ernst V. Arnold
DOCKET NO.:	00015-22306

CERTIFICATE OF DEPOSIT UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being transmitted via facsimile to the USPTO or being deposited with the United States Postal Service with sufficient postage as first class postage in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

12/4/07
Date of Deposit

Brenda Wiseman
Brenda Wiseman

APPELLANTS' APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop Appeal Brief – Patents

Sir:

Appellants submit this Appeal Brief in connection with their appeal from the final rejection of the Patent Office, mailed July 11, 2007, in the above-identified application. A Notice of Appeal was filed on October 4, 2007, which was received by the Board of Appeals on October 9, 2007.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest of this application is Albion International, Inc., 101 North Main Street, P.O. Box 750, Clearfield, UT 84015.

II. RELATED APPEALS AND INTERFERENCES

Appellants and Appellants' legal representatives know of no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 38-54 remain pending. Claim 1-37 have been canceled. The claims on appeal in this application are claims 38-54.

IV. STATUS OF AMENDMENTS

Claims 1-37 have been canceled since the Office Action mailed on February 9, 2007, by which the final rejection of the pending claims was made. The Amendment was entered on September 28, 2007. No other amendments have been made to the remaining pending claims.

V. SUMMARY OF CLAIMED SUBJECT MATTER

38. (previously presented) A method of preparing a hypoallergenic metal amino acid chelate composition (page 5, lines 27-28; page 10, lines 1-2), comprising:

a) selecting an amino acid source determined to be hypoallergenic (page 5, lines 28-29; page 10, lines 2-3);

b) selecting a metal source determined to be hypoallergenic (page 5, lines 29 – page 6, line 1; page 10, line 3); and

c) chelating an amino acid of the amino acid source to a metal of the metal source to form a hypoallergenic metal amino acid chelate composition (page 6, lines 1-2; page 10, lines 4-5).

46. (previously presented) A method of administering a metal amino acid chelate composition (page 6, line 6; page 10, lines 12-13), comprising:

a) identifying a subject susceptible to a type of allergic reaction (page 6, lines 7-8; page 10, lines 13-14);

b) formulating a metal amino acid chelate by (page 6, line 8; page 10, line 14):

i) selecting an amino acid source determined to be hypoallergenic with respect to the type of allergic reaction (page 6, lines 10-11; page 10, 16-17);

ii) selecting a metal source determined to be hypoallergenic with respect to the type of allergic reaction (page 6, lines 11-12; page 10, lines 17-19), and

iii) chelating an amino acid of the amino acid source to a metal of the metal source to form a hypoallergenic metal amino acid chelate composition (page 6, lines 12-14; page 10, lines 19-20); and

c) administering the hypoallergenic metal amino acid composition to the subject (page 6, lines 8-9; page10, line 15).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented for review are:

a. whether claims 38-40, 44-46, 48-49, and 52-54 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,504,055 (hereinafter "Hsu");

b. whether claims 38-40, 44-46, and 48-49 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,426,424 (hereinafter "Ashmead '424");

c. whether claims 38-40, 43-49, and 52-54 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,725,427 (hereinafter "Ashmead '427"); and

d. whether claims 41-42 and 50-51 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Ashmead '427 in view of "Production and Utilization of Amino Acids" published in Angewandte Chemie International Edition authored by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter "Izumi").

VII. ARGUMENT

A. Prosecution History

The present application was filed as an original utility application on April 21, 2004 under the title HYPOALLERGENIC METAL AMINO ACID CHELATES AND METAL AMINO ACID CHELATE-CONTAINING COMPOSITIONS. Fifty-four claims were presented. The application was assigned Serial No. 10/828,827.

In the first Office Action mailed February 10, 2006, the Examiner rejected claims 1-54. Specifically, the Examiner objected to the abstract as not commencing on a separate sheet in accordance with 37 C.F.R. 1.52(b)(4). The Examiner rejected claims 5-10 under U.S.C. § 112, second paragraph for typographical errors. Claims 1-4, 6-7, and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by "Infrared Spectra of Aqueous Solutions. I. Metal Chelate Compounds of Amino Acids" published in the Journal of the American Chemical Society authored by Kazuo Nakamoto, Yukiyoshi Morimoto, and Arthur E. Martell (JACS, 1961 83(22), 4528-4532) (hereinafter "Nakamoto"). Claims 1-4 and 12 were rejected under 35 U.S.C. § 102(b) as being anticipated by "Metal Chelating Tendencies of Glutamic and Aspartic Acids" published in the Journal of Physical Chemistry authored by R. F. Lumb and A. E. Martell (J. Phys. Chem., 1953 57(7), 690-693) (hereinafter "Lumb"). Claims 1-8, 19-21, 29-31, 38-40, 44-46, 48-49, and 52-54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,504,055 (hereinafter "Hsu"). Claims 1-9, 11, 19, 22-24, 28-31, 38-40, 44-46, and 48-49 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,426,424 (hereinafter "Ashmead '424"). Claims 1-4, 15-24, 26-31, 34-40, 43-49, and 52-54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 4,725,427 (hereinafter "Ashmead '427"). Claims 19 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hsu in

view of U.S. Pat. No. 6,299,896 (hereinafter "Cooper"). Claims 1, 13-14, 32-33, 41-42, and 50-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ashmead '427 in view of "Production and Utilization of Amino Acids" published in Angewandte Chemie International Edition authored by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter "Izumi"). Claims 1-13, 19-33, 38-42, 44-46, 48-51, and 53-54 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-13, 17-30, 33-37, 40-46, and 49-51 of copending Application No. 10/829,468.

Appellants submitted a response to the Patent Office on May 10, 2006. In that response, Appellants amended claims 10-15 to fix the typographical errors. Additionally, even though the abstract was on a separate sheet, Appellants submitted a new abstract. The Appellants argued that the existing 102 references did not teach each and every element of the invention as presently claimed. Specifically, Appellants argued that Lumb, Nakamoto, Hsu, Ashmkead '427, and Ashmead '424 do not teach hypoallergenic chelates. In fact, after reviewing the experimental conditions of Lumb and Nakamoto, Appellants contended that these two references do not provide chelates. Appellants also pointed out to the Examiner that none of the 5 references ever mention the term "hypoallergenic." Additionally, Appellants argued that the 103 references of Izumi and Cooper also failed to teach the hypoallergenic element of the pending claim set. Finally, Appellants submitted a terminal disclaimer in view of the double patenting provisional rejection.

A second Office Action was made final and mailed on July 24, 2006. In that Action, the Examiner withdrew the objection to the specification, the 112 rejections for claim 5-10, and the provisionally double-patenting rejection. However, the

Examiner maintained all of the previous 102 and 103 rejections. The Examiner argued that the chelates shown in the prior art were substantially identical to Appellants' chelates and noted that "patentability of a product does not depend on its method of production," (see OA page 3, 8), and noted "therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." See OA page 8. The Examiner then offered this cryptic statement "[w]ith respect to the method claims, the Examiner notes that the affirmative hypoallergenic determination steps and respectfully submits that the methods are taught by the prior art for the reason of record and those stated above." See OA page 12. Appellants' deem this "cryptic" since, prior to this statement, no other reasons had been given that would read on the present method claims.

Appellants submitted a response to the second Office Action along with a Request for Continued Examination (RCE) on October 24, 2006. Even though Appellants believed the claims to be clear and concise, Appellants amended the four independent claims to recite in the body that the composition is hypoallergenic rather than relying on the preamble and to clarify that the composition as a whole is hypoallergenic and not just the metal amino acid chelate molecule within the composition.

Additionally, Appellants provided the Examiner with the hypoallergenic definition in the specification and explained, in detail, that absent the present methods, the prior art teaches metal amino acid chelate compositions that are chemically different than the present metal amino acid compositions. Furthermore, the Appellants reminded the Examiner the applying the product-by-process standard (patentability of a product does not depend on its method of production) to the method claims was inappropriate. Appellants further inquired as to the "reasons of record"

the Examiner referred to, since no reasons had been given as to the method claims. Finally, Appellants contended that none of the cited art taught an affirmative hypoallergenic determination step as recited by the method claims.

In a third Office Action mailed February 7, 2007, the Examiner maintained all of the previous rejections. The Examiner responded to Appellants arguments that, since Appellants had defined hypoallergenic to include those compositions where care has been taken in formulation and/or production to ensure minimal instance of allergic reactions in a target subject or class of subjects, the cited references could be classified as hypoallergenic as care was taken in their preparations. The Examiner made other comments such as, referring to Ashmead's chelates, "[i]t is the Examiner's position that someone had to taste the composition and report on the flavor, any subject can be susceptible to allergens upon exposure to allergens . . . ." Appellants assume that the Examiner is attempting to infer that since Ashmead did not report that its hypothetical taste-testers did not have an allergic reaction then Ashmead's chelates are hypoallergenic? Notably, the Ashmead '424 and Ashmead '427 patents belong to Appellants. Consequently, Appellants are intimately familiar with these patents and note that neither requires that they be hypoallergenic.

The Examiner also provided more detail as to the method rejections. Specifically, the Examiner noted that the hypoallergenic evaluation step can include reviewing manufacturer's literature, assaying the material to determine if it is hypoallergenic, or preparing the components to ensure they are hypoallergenic. The Examiner then states that since Lumb used a commercial source, i.e., J. T. Baker, such manufacturing information was available.

Appellants submitted a response to the Office Action on May 7, 2007. In that response, Appellants contended that the Examiner has not provided proper rejections

but has rejected the claim set based on his assumptions. Specifically, Appellants noted that the Examiner assumed that the procedures found in the cited references would necessarily remove allergens. Appellants argued that the Examiner's argument that "care was taken" in the prior art to produce their respective metal amino acids and inferring that a composition that is safe for human consumption is necessarily hypoallergenic is patently false. Appellants provided an analogy as it relates to baby formula (provided in more detail below in the discussion section).

Furthermore, for the record, Appellants note that the Examiner took one phrase out of Appellants' specification in an attempt to justify the Examiner's assumptions. Specifically, Appellants' note that the specification states not that "care is taken" but that "care has been taken in formulation and/or production **to ensure minimal instance of allergic reactions in a target subject or class of subjects**" (emphasis added). See Application, page 8, lines 12-29.

Appellants further addressed the Examiner's supposition that administration of the cited art compositions to individuals read upon the claim element of identifying a subject susceptible to a type of allergic reaction. Specifically, Appellants noted the possibility of a person have an allergic reaction is not a substitute for identifying a person as set forth in the present method claims.

In a fourth Office Action made Final, mailed July 11, 2007, the Examiner maintained all of the previous rejections. The Examiner reiterated previous arguments and comments. The Examiner argued that "absence of evidence to the contrary [the prior art] compositions are hypoallergenic. See OA, page 9. The Examiner then reiterates that care has been taken in the production of the prior art compositions and that qualifies them as hypoallergenic. The Examiner repeats that the hypoallergenic determination step recited in the method claims is anticipated by

Lumb, since Lumb used a commercial source which would have an analysis on the label. The Examiner also maintains that as Lumb recrystallized the amino acids such amino acid chelates would be hypoallergenic. The Examiner concludes with "**[s]imply because the references of record do not state that their compositions are hypoallergenic does not mean that they are not hypoallergenic.**" See OA page 10.

Appellants submitted a two month response to the Final Office Action on September 11, 2007. In that response, Appellants canceled all claims except for the currently pending method claims in order to put just the method claims in condition for appeal. On September 28, 2007, the Examiner entered the amendment to the claim set and maintained his rejections as to the method claims. As Appellants and the Examiner seem to have a fundamental difference in the applicability of the present references and standards to be applied to establish proper 102 and 103 rejections for the present method claims, Appellants filed a Notice of Appeal on October 4, 2007.

The Appellants recognize that the above-recited file history is long and detailed, but this is done to illustrate what the Appellants believe to be a general lack of understanding by the Examiner regarding the present invention and the appropriate standards in rejecting the present method claims under § 102 and § 103.

B. Appellants' invention

Appellants' invention provides methods of preparing a hypoallergenic metal amino acid chelate composition, comprising: a) selecting an amino acid source determined to be hypoallergenic; b) selecting a metal source determined to be hypoallergenic; and c) chelating an amino acid of the amino acid source to a metal of the metal source to form a hypoallergenic metal amino acid chelate composition.

Additionally, methods of administering a metal amino acid chelate composition can comprise a) identifying a subject susceptible to a type of allergic reaction; b) formulating a metal amino acid chelate by: i) selecting an amino acid source determined to be hypoallergenic with respect to the type of allergic reaction; ii) selecting a metal source determined to be hypoallergenic with respect to the type of allergic reaction, and iii) chelating an amino acid of the amino acid source to a metal of the metal source to form a hypoallergenic metal amino acid chelate composition; and c) administering the hypoallergenic metal amino acid composition to the subject.

C. The Asserted References

1. The Hsu Reference

Hsu teaches a method for producing a water soluble metal amino acid chelate. Such a method includes adding a metal salt to deaerated water, mixing the salt solution with a mixture of an amino acid and an organic acid and adjusting the pH of the composition to a range of from about 4.5 to about 8.5. See Abstract. Highly critical to the invention is the deareation of the water used to produce the chelates. See col. 3, lines 14-15. Hsu discloses the chelate structure "believed to be" a 5-membered ring. See col. 3, lines 27-37. Notably, Hsu never mentions the use of hypoallergenic starting materials, that the resulting chelates are hypoallergenic, that

such amino acid chelates are used in preparing hypoallergenic compositions, or that these hypoallergenic amino acid chelates can be administered to subjects that may be susceptible to allergic reactions. In fact, the chelates in Hsu are generally directed for administration to plants. See Abstract; col. 3, lines 8-13; col. 7 line 42 – col. 10, line 63.

2. The Ashmead '424 Reference

Ashmead '424 teaches compositions and methods for preparing amino acid chelates by blending hydrated metal sulfate salts, amino acid ligands, and reaction modifiers; confining the particulate blend in an enclosed environment; and applying heat to the particulate environment. See Abstract. Notably, Ashmead '424 never mentions the use of hypoallergenic starting materials, that the resulting chelates are necessarily hypoallergenic, that such amino acid chelates are used in hypoallergenic compositions, or that these hypoallergenic amino acid chelates can be administered to subjects that may be susceptible to allergic reactions.

3. The Ashmead '427 Reference

Ashmead '427 teaches methods and compositions containing vitamins and amino acid chelates. The composition can have 20-30% of a vitamin blend, 5-25% amino acid chelated materials, 20-45% citric acid, 5-25% of alkali or alkaline earth metals, 1-5% flavoring agent, and 0.5-2% sweetening agent. See Abstract. Notably, Ashmead '427 never mentions the use of hypoallergenic starting materials, that the resulting chelates are necessarily hypoallergenic, that such amino acid chelates are used in hypoallergenic compositions, or that these hypoallergenic amino acid chelates can be administered to subjects that may be susceptible to allergic reactions.

4. The Izumi Reference

Izumi reviews methods for producing amino acid chelates such as extraction from protein hydrolyzates, fermentation with the aid from microorganisms, enzymatic processes, and chemical synthesis. See Abstract. Notably, Izumi never mentions the use of hypoallergenic starting materials, that the resulting chelates are hypoallergenic, that such amino acid chelates are used in hypoallergenic compositions, or that these hypoallergenic amino acid chelates can be administered to subjects that may be susceptible to allergic reactions.

D. Rejections Under 35 U.S.C. § 102(b)

1. Requirements for Prima Facie anticipation

The Examiner has rejected claims 38-40, 43-49, and 52-54 under § 102(b), all or in part, as being *prima facie* anticipated by a number of references. Before discussing the rejection, it is thought proper to briefly state what is required to sustain such a rejection. It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). In order to establish anticipation under 35 U.S.C. 102, all elements of the claim must be found in a single reference. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987). In particular, as pointed out by the court in *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1981), *cert denied,* 469 U.S. 851 (1984), "anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference." "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989).

Further, as the Examiner is relying on inherency rather than a direct teaching, it is notable that in order to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Even if a prior art reference is capable of being modified and the modification would anticipate the invention, this is not sufficient to support an anticipation rejection based on inherency. As the Examiner is particularly relying on this doctrine, Appellants wish to provide the Board with applicable case law. Specifically, the Federal Circuit Court

of Appeals stated "[u]nder the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element 'is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill' (citations omitted). Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002). The Court further states that "'[i]nherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art'" (citations omitted). Id. As such, Appellants submit that the appropriate standard in establishing an anticipatory rejection through inherency has been well defined by the courts.

With the above background in mind, Appellants contend that the Examiner has not met this burden with respect to any of the claims on appeal. Particularly, Appellants submit that the PTO has failed to show that each and every element of the claimed invention is contained in any of the cited references. Appellants now turn to a discussion of the individual rejections at issue, and the references on which they are based.

2. The rejection of Claims 38-40, 44-46, 48-49, and 52-54 by Hsu

The Examiner has rejected claims 38-40, 44-46, 48-49, and 52-54 by Hsu. However, Hsu does not provide a method of preparing or administering a hypoallergenic metal amino acid chelate composition. In rejecting the present method claims by Hsu, the Examiner has stated that "[i]t is the Examiner's position that the method of Hsu et al. is the same as that claimed in instant claim 52, i.e., it results in the same composition. See Final OA, dated July 11, 2007, page 5. However, such a statement shows a fundamental lack of understanding by the Examiner as to the correct standard in rejecting the present method claims.

Before discussing the Examiner's arguments and Appellants' responses, Appellants note that the following discussion is equally applicable to the Ashmead '424, Ashmead '427, and the Izumi references. As such, Appellants ask the Board to consider these arguments with respect to each of the rejections contained herein.

Throughout the present prosecution, Appellants have attempted to explain the correct standard needed to establish anticipation. The Appellants have submitted the above 102 case law to the Examiner and have argued that the Examiner must show each and every element in rejecting the present method claims. Additionally, Appellants have explained that the product-by-process inquiry cited by the Examiner throughout the prosecution does not apply to method claims, i.e., patentability of a method is independent of patentability of a product. Appellants have explained that a single product may be produced by a number of patentable methods. However, Appellants are unsure if the Examiner has considered this critical difference as the Examiner has maintained the present 102 rejections using the same logic.

Notably, the Examiner has never argued that any of the presently cited references explicitly teach a hypoallergenic composition. Instead, at best, the Examiner is relying on inherency. As such, in order to establish a *prima facie* case for a proper 102 rejection, the Examiner must show that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. However, the Examiner has not done so in rejecting the present method claims.

There are several "missing descriptive matters" in the present case for both independent method claims. For claim 38, none of the cited art teaches selecting an amino acid determined to be hypoallergenic or selecting a metal source determined to be hypoallergenic. The hypoallergenic determination is critical in providing a

hypoallergenic metal amino acid chelate composition that is know to be hypoallergenic. For claim 46, none of the cited art teaches identifying a subject susceptible to a type of allergic reaction; formulating a metal amino acid chelate by selecting an amino acid determined to be hypoallergenic and selecting a metal source determined to be hypoallergenic; or administering the hypoallergenic metal amino acid chelate composition to a subject.

To be clear, both independent claims 38 and 46 specifically require an affirmative hypoallergenic determination steps with respect to both the amino acid source and the metal source. The present specification is specific in defining the terms hypoallergenic, allergy, and allergen, so that no ambiguity arises as to the Appellants' methods and compositions. Specifically,

> "hypoallergenic" refers to compositions where care has been taken in formulation and/or production to ensure minimal instance of allergic reactions in a target subject or class of subjects. . .
> "[a]llergy" refers to an acquired and abnormal immune response to a substance or moiety of a substance (allergen) that produces an altered bodily reaction. . .
> "allergen" refers to a substance that causes manifestations of allergy, such as a protein or antigen.

See page 8, lines 12-29. Elaborating on this affirmative hypoallergenic determination, the specification states that "[d]etermining whether a composition or its source is hypoallergenic indicates that some type of evaluative step be performed." See page 10, lines 21-28. None of the references provided by the Examiner refers to any such "evaluative step" as required by claims 38 and 46.

In regards to this, the Examiner has addressed the "evaluative step" and argued that

> "all that is required for determining whether a composition or its source is hypoallergenic indicates that some type of evaluative step be performed. For example, in determining whether an amino acid, including its source, as well as a metal source is hypoallergenic, an evaluation step can include steps such as reviewing literature or interviewing manufacturers associated with a product obtained from a third party, preparing the compositions or sources oneself to ensure that all components are hypoallergenic, and/or conducting an assay to verify that a composition is truly hypoallergenic." See Final OA dated July 11, 2007, page 10.

The Examiner then refers to Lumb since Lumb used a commercial source from J. T. Baker, which allegedly has a label identifying purity and contaminants.

However, such disclosure does not anticipate the present method claims. In fact, such a disclosure doesn't even anticipate a single element of the present method claims. First, the Examiner cites a reference that was never used to reject the present method claims (Lumb was used to reject former compositional claims 1-4 and 12, which have been canceled). As such, the Examiner's use of the Lumb reference in rejecting the present method claims is inappropriate.

Second, Even if a reference uses a commercial source that has a label, such disclosure has absolutely no bearing on whether an affirmative hypoallergenic determination has been made by the chelate manufacturer. To be clear, there is absolutely no other disclosure in Lumb that would indicate that the materials used qualify as hypoallergenic. Furthermore, and perhaps more importantly, there is absolutely no disclosure or teaching in Lumb regarding methods of making hypoallergenic compositions. Appellants wish to stress that the claims do not merely recite a hypoallergenic metal amino acid chelate molecule, but that the entire composition is hypoallergenic, which includes the metal amino acid chelate molecule

and other materials that are typically not completely removed, e.g., unreacted amino acid, unreacted metal, etc. Further, it should be noted that amino acids are typically provided by hydrolysis of protein, which of itself, can be a problem with respect to containing allergens that are not totally removed. This is why selecting sources that are hypoallergenic to begin with is so significant with respect to the claimed methods. As such, Appellants contend that the Examiner has not shown each and every element of the present method claims and has not applied the appropriate standard in order to establish a *prima facie* 102 rejection.

Furthermore, the Examiner has emphatically stated "**[s]imply because the references of record do not state that their compositions are hypoallergenic does not mean that they are not hypoallergenic.**" See Final Office Action dated July 11, 2007, page 10, last sentence. Such a statement only serves as an admission that the present references lack the element of a hypoallergenic determination. As such, the Examiner is solely relying on inherency, and, as previously discussed, an inherency argument must show that the missing descriptive matter is necessarily present. Clearly, that is not the case here since the Examiner has relied upon the mere possibility of the referenced compositions being hypoallergenic. Such a possibility clearly defeats the "necessity" element in establishing anticipation by inherency. As the Federal Circuit Court of Appeals has stated "[i]nherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art." Rosco, 304 F.3d at 1380.

In addition to the method of making a hypoallergenic metal amino acid chelate composition, the Examiner has not shown the additional elements associated with the method of administering such a composition. Specifically, the Examiner has failed to

show the elements of identifying a subject susceptible to a type of allergic reaction and administering the hypoallergenic metal amino acid composition to the subject.

The Examiner has addressed the first element in the following manner. "It is the Examiner's position that any subject is susceptible to a type of allergic reaction" and that the identifying steps are "not explicitly recited in the art they are nevertheless simply intrinsic in the art." See Final Office Action dated July 11, 2007, page 11, 1st paragraph. Appellants find such incoherent logic difficult to address; however, Appellants submit that allergic reactions are unique and specific and that the Examiner's overly broad statement is incorrect. The fact that a person may be allergic to any given substance is not a substitute for "identifying a subject susceptible to a type of allergic reaction." As such, Appellants have recited an element not taught in any of the presently cited references. Additionally, Appellants note that as the references never identified subjects susceptible to an allergic reaction, the references cannot teach the element of administering a hypoallergenic metal amino acid composition to such a subject.

Appellants also wish to address the Examiner's use of Appellants' hypoallergenic definition from Appellants' specification. Appellants note that the Examiner used Appellants' definition in rejecting the compositional claims; however, Appellants assume that the Examiner would also deem it applicable to the method claims. As previously discussed, "hypoallergenic" refers to compositions where care has been taken in formulation and/or production to ensure minimal instance of allergic reactions in a target subject or class of subjects." See Appellants specification, page 8, lines 12-18.

With respect to this definition, the Examiner has focused on the phrase "where care has been taken" in stating "[i]t is the Examiner's position that care has been

taken in the formulation of the metal amino acid chelates of the cited references such that the metal amino acid chelates would be substantially free of impurities (for example allergens) that could potentially interfere with the sensitive types of analysis performed on the metal amino acid chelates." See Final Office Action dated July 11, 2007, pages 9-10. However, the Examiner has taken the phrase "care has been taken" out of context. Appellants have clearly defined that care has been taken "to ensure minimal instance of allergic reactions in a target subject or class of subjects." Such is not the case with the present cited references. There is simply no disclosure in any of the references that ensure a minimal instance of allergic reactions. In fact, as previously discussed, none of the references mention hypoallergenic materials or hypoallergenic compositions in any context. Again, it is noted that the claims are drawn to the chelate composition, and not the individual chelate molecule. In practicality, a chelate molecule does not exist in a vacuum, but rather, many chelate molecules are commingled with unreacted starting material and other material that leads to allergic reaction. This is particularly true with amino acids, as they are typically prepared using proteins, which are notorious allergens. By selecting source material to begin with that is substantially devoid of such allergens, amino acid chelate compositions can be prepared that do not illicit allergic reactions in susceptible subjects.

Appellants wish to further elaborate on this point using a commonly used hypoallergenic product (this was submitted to the Examiner during prosecution). Baby formula is produced by a number of companies including Similac. Appellants submit that Similac takes great care in the manufacturing of its products. However, Similac offers various forms of its baby formula including a regular formula, Similac Advance Infant Formula, and a hypoallergenic formula, Similac Alimentum

Hypoallergenic Formula. See http://welcomeaddition.com. Such formulations are not interchangeable. As such, Appellants submit that the mere ability to be consumed by a human or the fact that care is taken in production is not enough to ensure a hypoallergenic composition. Furthermore, Appellants stress that merely taking care in producing and/or manufacturing a product is not enough to qualify under Appellants' hypoallergenic definition. Appellants contend that the Examiner is attempting to take this one phrase from Appellants' hypoallergenic definition and use it out of context.

As the Examiner has not provided any single reference that provides each and every element of the present claims, Appellants respectfully requests that current 102 rejections be overturned. Additionally, as Appellants has explained the novelty of the independent method claims over the prior art, Appellants respectfully requests that the 102 rejections for the corresponding dependent claims be overturned as well.

3. The rejection of Claims 38-40, 44-46, and 48-49 by Ashmead '424

The Examiner has rejected claims 38-40, 44-46, and 48-49 by Ashmead '424. However, Ashmead '424 does not provide a method of preparing or administering a hypoallergenic metal amino acid chelate composition. In rejecting the present method claims by Asmead '424, the Examiner merely states that Ashmead '424 produced a metal amino acid chelate. However, such a disclosure fails to provide the elements of claims 38 or 46.

For claim 38, Ashmead '424 does not teach selecting an amino acid determined to be hypoallergenic or selecting a metal source determined to be hypoallergenic.

For claim 46, Ashmead '424 does not teach identifying a subject susceptible to a type of allergic reaction; formulating a metal amino acid chelate by selecting an

amino acid determined to be hypoallergenic and selecting a metal source determined to be hypoallergenic; or administering the hypoallergenic metal amino acid chelate composition to a subject.

Appellants renew the above arguments under Hsu. Specifically, Appellants contend that the Examiner is solely relying on inherency, as the Examiner has admitted that the hypoallergenic determination is not explicitly stated in any of the references. Furthermore, Appellants submit that the Examiner has relied upon the mere possibility of the referenced compositions being hypoallergenic. Such a possibility clearly defeats the "necessity" element in establishing anticipation by inherency. As the Federal Circuit Court of Appeals has stated "[i]nherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art." Rosco, 304 F.3d at 1380.

As the Examiner has not provided any single reference that provides each and every element of the present claims, Appellants respectfully requests that current 102 rejection be overturned. Furthermore, as Appellants has explained the novelty of the independent method claims over the prior art, Appellants respectfully requests that the 102 rejections for the corresponding dependent claims be overturned as well.

4. The rejection of Claims 38-40, 43-49, and 52-54 by Ashmead '427

The Examiner has rejected claims 38-40, 43-49, and 52-54 by Ashmead '427. However, Ashmead '427 does not provide a method of preparing or administering a hypoallergenic metal amino acid chelate composition. In rejecting the present method claims by Asmead '427, the Examiner merely states that Ashmead '427 produced a vitamin and mineral composition containing a metal amino acid chelate. However, such a disclosure fails to provide the elements of claims 38 or 46.

For claim 38, Ashmead '427 does not teach selecting an amino acid determined to be hypoallergenic or selecting a metal source determined to be hypoallergenic.

For claim 46, Ashmead '427 does not teach identifying a subject susceptible to a type of allergic reaction; formulating a metal amino acid chelate by selecting an amino acid determined to be hypoallergenic and selecting a metal source determined to be hypoallergenic; or administering the hypoallergenic metal amino acid chelate composition to a subject.

Appellants renew the above arguments under Hsu. Specifically, Appellants contend that the Examiner is solely relying on inherency as the Examiner has admitted that the hypoallergenic determination is not explicitly stated in any of the references. Furthermore, Appellants submit that the Examiner has relied upon the mere possibility of the referenced compositions being hypoallergenic. Such a possibility clearly defeats the "necessity" element in establishing anticipation by inherency. As the Federal Circuit Court of Appeals has stated "[i]nherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art." Rosco, 304 F.3d at 1380.

As the Examiner has not provided any single reference that provides each and every element of the present claims, Appellants respectfully requests that current 102 rejection be overturned. Furthermore, as Appellants has explained the novelty of the independent method claims over the prior art, Appellants respectfully requests that the 102 rejections for the corresponding dependent claims be overturned as well.

E. Rejections Under 35 U.S.C. § 103(a)

1. Requirements for Prima Facie obviousness

The Examiner has rejected all of the pending claims under § 103(a) as being *prima facie* obvious over a number of references. The Patent and Trademark Office (PTO), through the Examiner, has the burden of establishing a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1998). To satisfy this burden, the PTO must meet the criteria set out in M.P.E.P. § 706.02(j):

> [T]hree basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Moreover, the obviousness analysis must comply with the statutory scheme as explained by the Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), namely, consideration must be given to: (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of ordinary skill in the pertinent art, and (4) additional evidence, which may serve as indicia of non-obviousness. Appellants note that nothing in the recent *KSR* Supreme Court case changes this basic analysis.

An excellent summary of how the prior art must be considered to make a case of *prima facie* obviousness is contained in *In re Ehrreich et al.*, 220 U.S.P.Q. 504, 509-511 (CCPA 1979). There the court states that a reference must not be considered in a vacuum, but against the background of the other references of record. It is stated that the question of a § 103 case is what the reference(s) would "collectively suggest" to one of ordinary skill in the art. However, the court specifically cautioned that the

Examiner must consider the entirety of the disclosure made by the reference and avoid combining them indiscriminately.

In finding that the "subject matter as a whole" would not have been obvious in *Ehrreich* the court concluded:

> "Thus, we are directed to no combination of prior art references which would have rendered the claimed subject matter as a whole obvious to one of ordinary skill in the art at the time the invention was made. The PTO has not shown the existence of all the claimed limitations in the prior art or any suggestion leading to their combination in the manner claimed by applicants." (underlining added)

It has been widely recognized that virtually every invention is a combination of elements and that most, if not all, of these will be found somewhere in an examination of the prior art. This reasoning lead the court, in *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983) to state:

> "...it is common to find elements or features somewhere in the prior art. Moreover, most if not all elements perform their ordained and expected function. The test is whether the claimed invention as a whole, in light of all the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made." (underlining added)

With the above background in mind, Appellants contend that the Examiner has not met this burden with respect to any of the claims on appeal. Particularly, Appellants submit that the PTO has failed to show that each and every element of the claimed invention is contained in the combined references. Appellants now turn to a discussion of the individual rejections at issue, and the references on which they are based.

2. The rejection of Claims 41-42 and 50-51 over Ashmead '427 in view of Izumi

According to M.P.E.P. § 706.02(j), to render a claim *prima facie* obvious, the asserted prior art reference (or references when combined) must teach or suggest all of the claim limitations. Appellants submit that the present combination asserted by the Examiner does not teach or suggest each and every element of the rejected claims. The Appellants have argued repeatedly, that none of the cited references teach each and every element of the present method claims, alone or in combination.

The Examiner has admitted that Ashmead '427 does not teach a method other than protein hydrolysis or protein hydrolysis where the protein used in the hydrolysis is hypoallergenic. The Examiner then alleges that Izumi teaches these elements. However, such an allegation is without merit.

Specifically, with respect to claims 42 and 51, Appellants note that Izumi never discloses or teaches protein hydrolysis where the protein is hypoallergenic. In fact, the Examiner never cited the alleged passage where such alleged hypoallergenic protein is discussed. Additionally, even though Izumi discloses various techniques for producing amino acids, Izumi does not teach or disclose each and every element of claims 38 and 46, from which claims 41-42 and 50-51 respectively depend.

For claim 38, neither Ashmead '427 nor Izumi teach selecting an amino acid determined to be hypoallergenic or selecting a metal source determined to be hypoallergenic.

For claim 46, neither Ashmead '427 nor Izumi teach identifying a subject susceptible to a type of allergic reaction; formulating a metal amino acid chelate by selecting an amino acid determined to be hypoallergenic and selecting a metal source

determined to be hypoallergenic; or administering the hypoallergenic metal amino acid chelate composition to a subject.

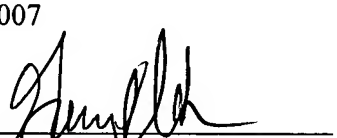
Because the asserted combination fails to teach every element of claims 41-42 and 50-51, Appellants submit that these claims present patentable subject matter, and that the rejections of these claims should be overturned.

F. Conclusion

Appellants respectfully submit that the claims on appeal set forth in the Appendix are patentably distinct from the asserted prior art references. Particularly, none of the asserted references teach each and every element as required by 35 U.S.C. § 102(b). Additionally, Appellants contend that Ashmead '427 in combination with Izumi fails to teach each and every element of the claimed invention, and that a *prima facie* case of obviousness under 35 U.S.C. § 103(a) has not been established.

For at least these reasons, Appellants respectfully request that the Board of Appeals reverse the rejection and remand the case to the Examiner for allowance.

Dated this 4th day of December, 2007



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VIII. CLAIMS APPENDIX

1-37. (canceled).

38. (previously presented) A method of preparing a hypoallergenic metal amino acid chelate composition, comprising:

a) selecting an amino acid source determined to be hypoallergenic;

b) selecting a metal source determined to be hypoallergenic; and

c) chelating an amino acid of the amino acid source to a metal of the metal source to form a hypoallergenic metal amino acid chelate composition.

39. (original) A method as in claim 38, wherein during the step of selecting the amino acid source, if a first amino acid source is not hypoallergenic, additional amino acid sources are evaluated until a hypoallergenic amino acid source is ascertained.

40. (original) A method as in claim 38, wherein during the step of selecting the metal source, if a first metal source is not hypoallergenic, additional metal sources are evaluated until a hypoallergenic metal source is ascertained.

41. (original) A method as in claim 38, wherein the amino acid source is not prepared by protein hydrolysis.

42. (original) A method as in claim 38, wherein the amino acid source is prepared by protein hydrolysis, and wherein the protein used in the hydrolysis is hypoallergenic.

43. (original) A method as in claim 38, wherein the amino acid source is rendered hypoallergenic after formation, but before chelation with the metal.

44. (original) A method as in claim 38, further comprising selecting an additive determined to be hypoallergenic, and including the additive as a mixture with the hypoallergenic metal amino acid chelate.

45. (original) A method as in claim 44, wherein the additive is selected from the group consisting of hypoallergenic organic acids, hypoallergenic free amino acids, hypoallergenic amino acid salts, hypoallergenic fillers, hypoallergenic flow control agents, hypoallergenic lubricants, hypoallergenic flow agents, hypoallergenic hydroscopicity reducing agents, hypoallergenic pH control agents, hypoallergenic catalysts, hypoallergenic vitamins, hypoallergenic dust control agents, hypoallergenic binders, hypoallergenic disintegrating agents, hypoallergenic flavoring agents, hypoallergenic flavoring agents, hypoallergenic taste-reducing agents, hypoallergenic capsule shells, hypoallergenic shellacs, hypoallergenic waxes, hypoallergenic gelatin sources, hypoallergenic emulsifiers, hypoallergenic oils, and combinations thereof.

46. (previously presented) A method of administering a metal amino acid chelate composition, comprising:

a) identifying a subject susceptible to a type of allergic reaction;

b) formulating a metal amino acid chelate by:

i) selecting an amino acid source determined to be hypoallergenic with respect to the type of allergic reaction;

ii) selecting a metal source determined to be hypoallergenic with respect to the type of allergic reaction, and

iii) chelating an amino acid of the amino acid source to a metal of the metal source to form a hypoallergenic metal amino acid chelate composition; and

c) administering the hypoallergenic metal amino acid composition to the subject.

47. (original) A method as in claim 46, wherein the subject is allergic to at least one of soy, peanuts, tree nuts, crustaceans, finfish, dairy, wheat, eggs, corn, gelatin, whey, chocolate, and strawberries.

48. (original) A method as in claim 46, wherein during the step of selecting the amino acid source, if a first amino acid source is not hypoallergenic, additional amino acid sources are evaluated until a hypoallergenic amino acid source is ascertained.

49. (original) A method as in claim 48, wherein during the step of selecting the metal source, if a first metal source is not hypoallergenic, additional metal sources are evaluated until a hypoallergenic metal source is ascertained.

50. (original) A method as in claim 46, wherein the amino acid source is prepared by a method other than protein hydrolysis.

51. (original) A method as in claim 46, wherein the amino acid source is prepared by protein hydrolysis, and wherein the protein used in the hydrolysis is hypoallergenic.

52. (original) A method as in claim 46, wherein the amino acid source is rendered hypoallergenic after formation, but before chelation with the metal.

53. (original) A method as in claim 46, further comprising steps of selecting an additive determined to be hypoallergenic, and including the additive as a mixture with the hypoallergenic metal amino acid chelate.

54. (original) A method as in claim 52, wherein the additive is selected from the group consisting of hypoallergenic organic acids, hypoallergenic free amino acids, hypoallergenic amino acid salts, hypoallergenic fillers, hypoallergenic flow control agents, hypoallergenic lubricants, hypoallergenic flow agents, hypoallergenic hydroscopicity reducing agents, hypoallergenic pH control agents, hypoallergenic catalysts, hypoallergenic vitamins, hypoallergenic dust control agents, hypoallergenic binders, hypoallergenic disintegrating agents, hypoallergenic flavoring agents, hypoallergenic flavoring agents, hypoallergenic taste-reducing agents, hypoallergenic capsule shells, hypoallergenic shellacs, hypoallergenic waxes, hypoallergenic gelatin sources, hypoallergenic emulsifiers, hypoallergenic oils, and combinations thereof.

IX. EVIDENCE APPENDIX

(No matter presented)

X. RELATED PROCEEDINGS APPENDIX

(No matter presented)